Protecting Infants from Respiratory Syncytial Virus (RSV)

Clinician Outreach and Communication Activity (COCA) Call

Thursday, October 26, 2023

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- Instructions on how to earn continuing education will be provided at the end of the call.

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Objectives

At the conclusion of today's session, the participant will be able to accomplish the following:

1. Review current RSV epidemiology in infants.
2. Describe the safety of nirsevimab and the maternal RSV vaccine.
3. Discuss CDC's latest recommendations and clinical considerations for administering RSV immunizations in infants under 8 months, toddlers at increased risk for severe illness due to RSV, and pregnant people.
4. List implementation considerations for nirsevimab and the maternal RSV vaccine, including updates for the Vaccines for Children (VFC) program.

To Ask a Question

- Using the Zoom Webinar System
  - Click on the “Q&A” button
  - Type your question in the “Q&A” box
  - Submit your question

- If you are a patient, please refer your question to your healthcare provider.

- If you are a member of the media, please direct your questions to CDC Media Relations at 404-639-3286 or email media@cdc.gov.

Today's Presenters

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Respiratory Syncytial Virus (RSV) Immunization Recommendations to Protect Infants and Children

Jefferson Jones MD MPH FAAP
CDR, US Public Health Service

Co-Lead, ACIP Pediatric/Maternal RSV Work Group
Coronavirus and Other Respiratory Viruses Division
National Center for Immunization and Respiratory Diseases

October 26, 2023

Outline

- RSV epidemiology in children
- Efficacy and safety of nirsevimab and Pfizer maternal RSV vaccine
- Recommendations and clinical guidance for healthcare facilities, assuming sufficient nirsevimab availability
- Shortage of nirsevimab and interim recommendations for healthcare facilities with limited availability

Respiratory Syncytial Virus (RSV) Epidemiology in Children

RSV is the leading cause of hospitalization in U.S. infants[1]

- Most (68%) infants are infected in the first year of life and nearly all (97%) by age 2 years[2]
- 2–3% of young infants will be hospitalized for RSV[3,4,5]
- RSV is a common cause of lower respiratory tract infection in infants
- Highest RSV hospitalization rates occur in first months of life and risk declines with increasing age in early childhood[3,5]
- Although medical conditions are associated with increased risk of severe disease, 79% of children hospitalized with RSV aged <2 years had no underlying medical conditions[3]

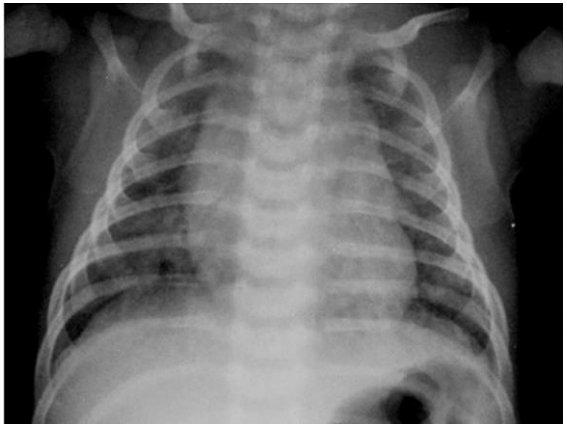
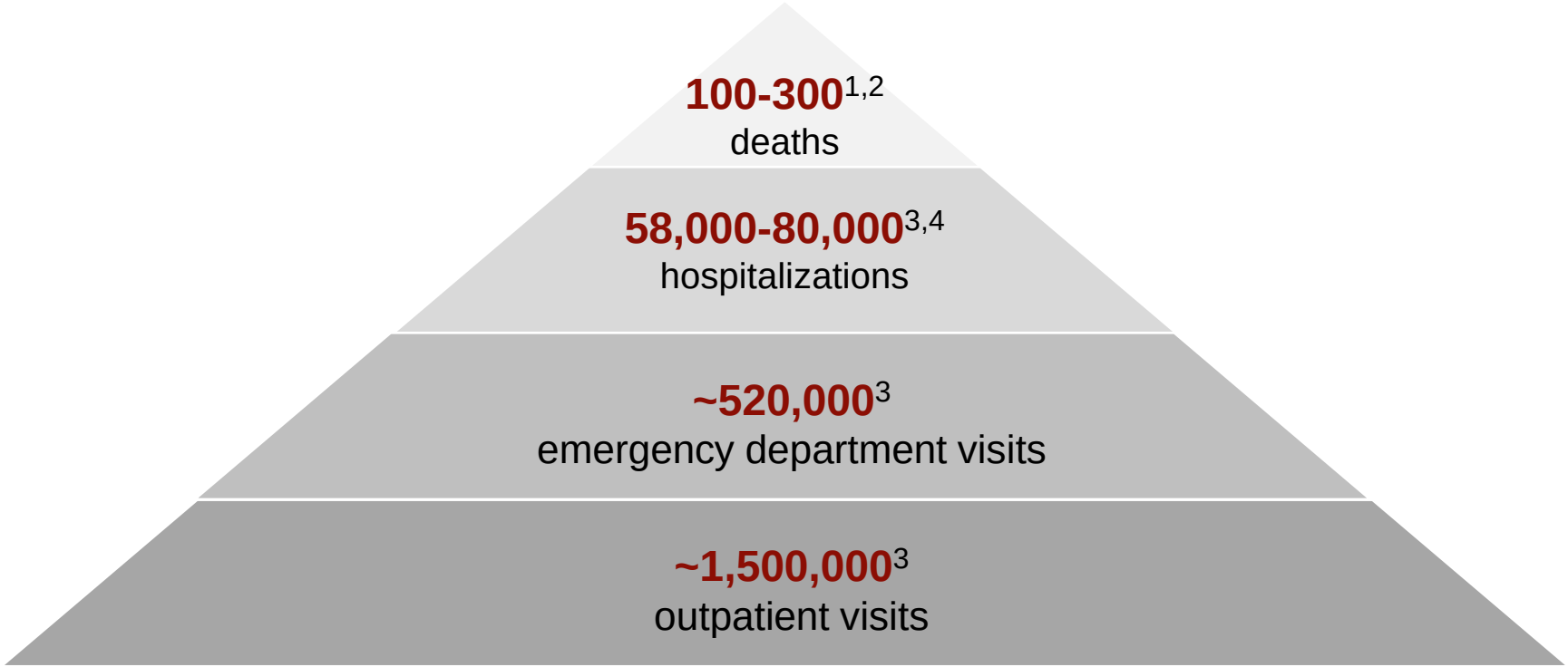


Image: Goncalves et al. Critical Care Research and Practice 2012

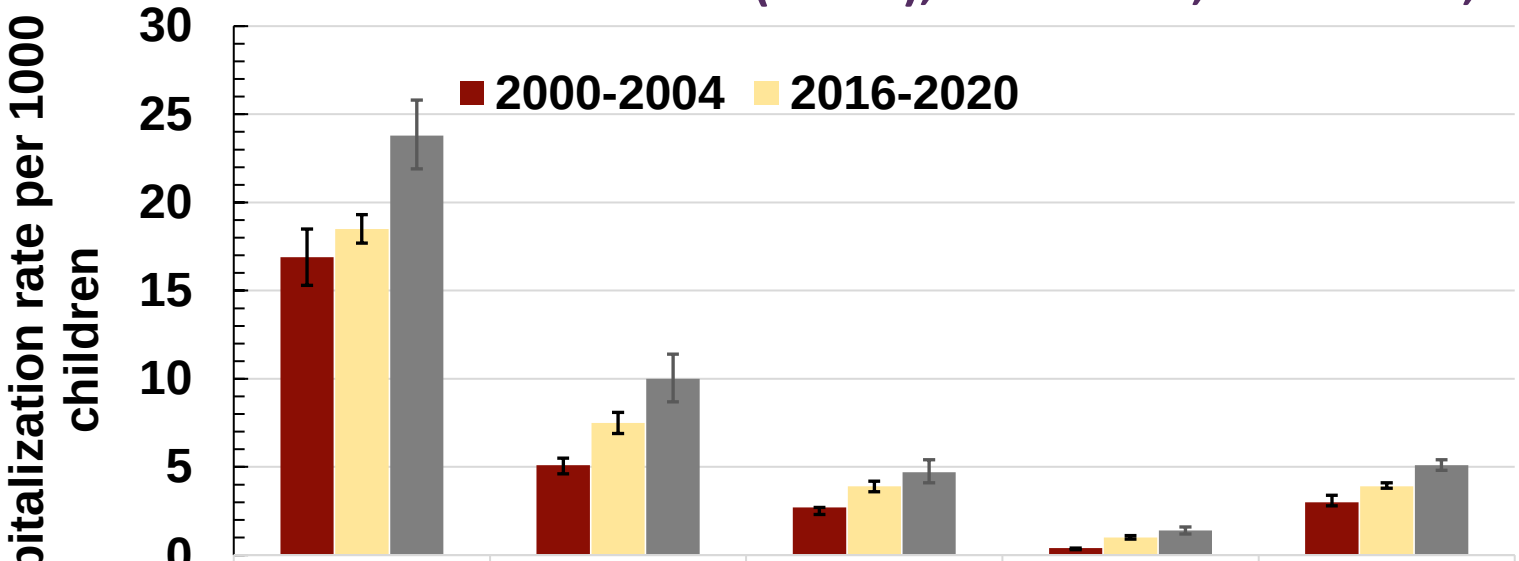
- [1]Suh et al. JID 2022; [2]Glezen et al, Arch Dis Child, 1986; [3]Hall et al, Pediatrics, 2013; [4]Langley & Anderson, PIDJ, 2011; [5]CDC NVSN data

Each year in U.S. children younger than 5 years, RSV is associated with…



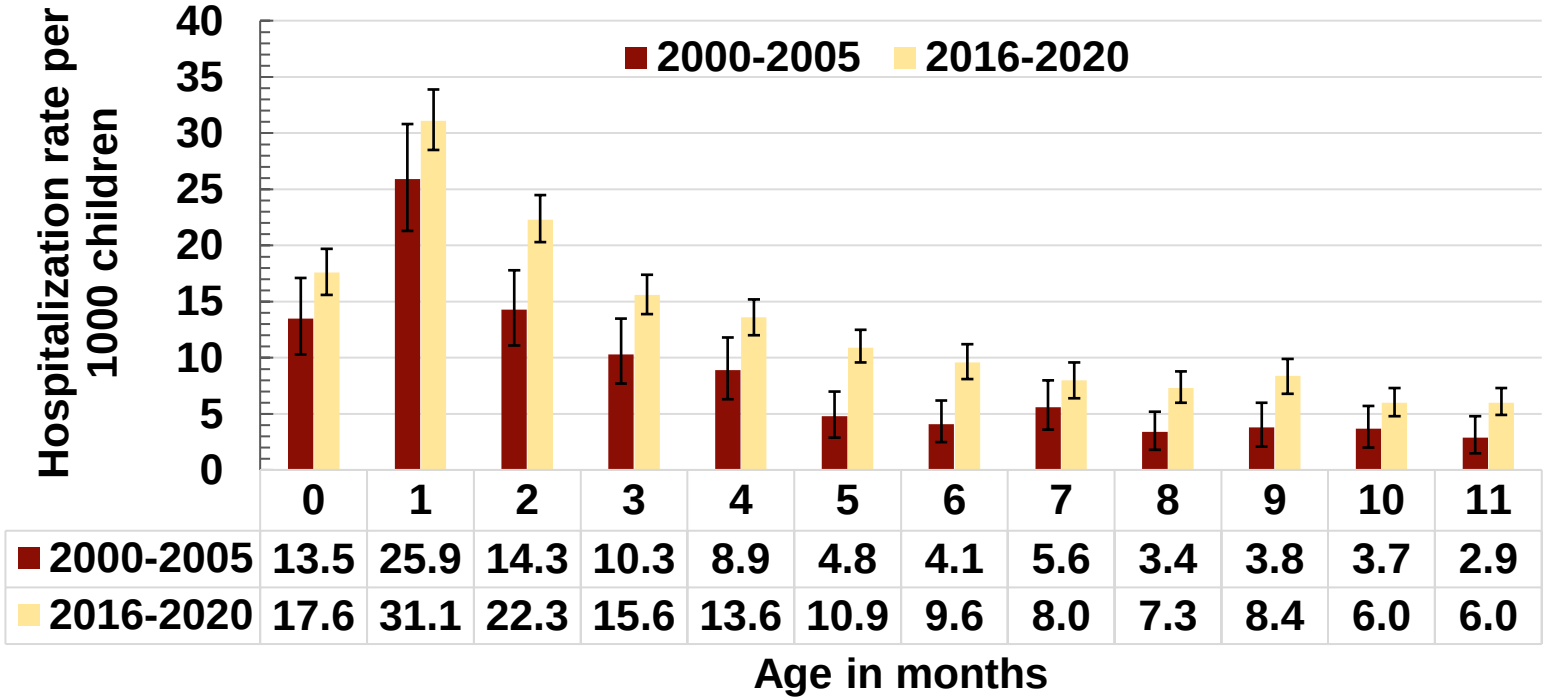
[1]Thompson et al, JAMA, 2003; [2]Hansen et al, JAMA Network Open, 2022; [3]Hall et al, NEJM, 2009; [4]McLaughlin et al, J Infect Dis, 2022 (*estimate 80,000 hospitalizations in infants <1y)

RSV-associated hospitalization rates in children younger than 5 years, New Vaccine Surveillance Network (NVSN), 2000-2004, 2016-2020, 2021



	0-5 months	6-11 months	12-23 months	24-59 months	0-59 months
2000-2004	16.9	5.1	2.7	0.4	3
2016-2020	18.5	7.5	3.9	1.0	3.9
2021	23.8	10.0	4.7	1.4	5.1

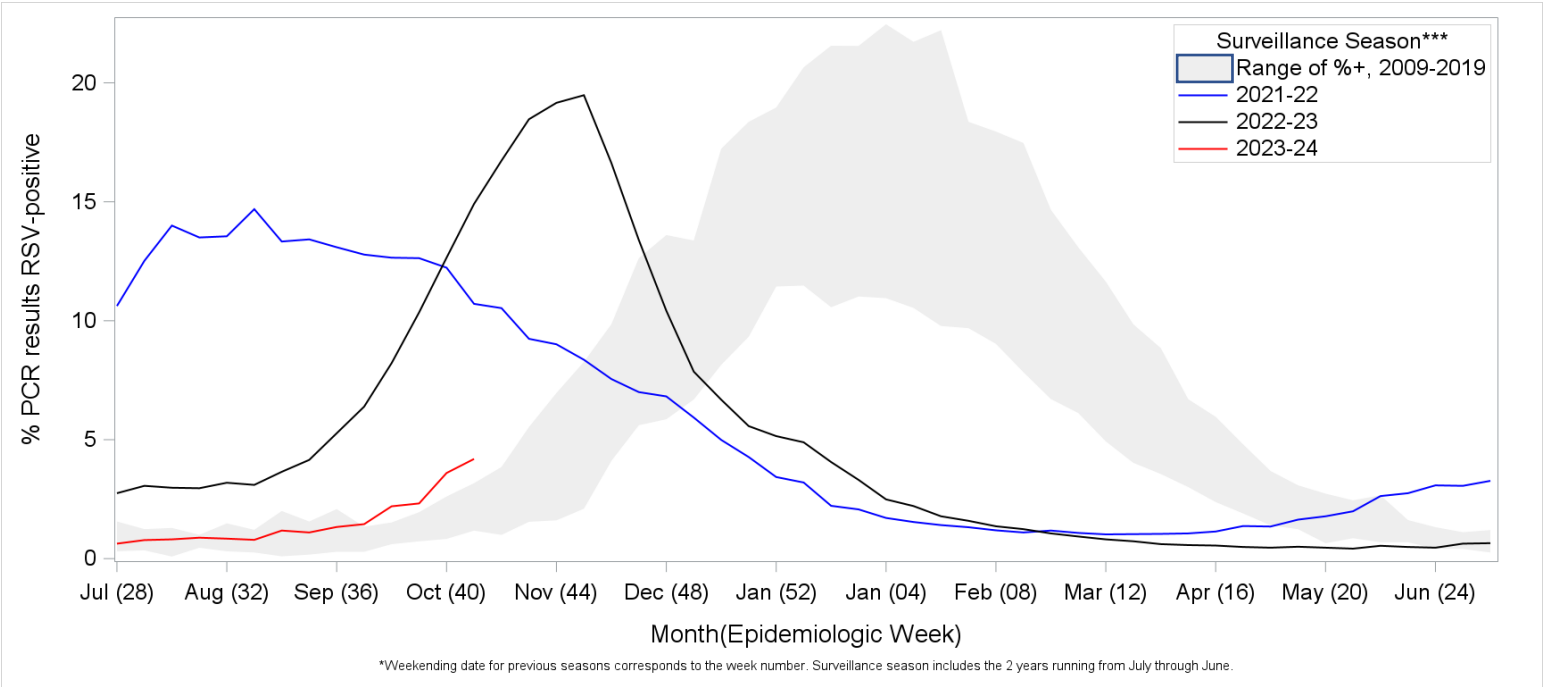
RSV-associated hospitalization rates in children aged 0–11 months, NVSN, 2000–2005 and 2016–2020



	0	1	2	3	4	5	6	7	8	9	10	11
2000-2005	13.5	25.9	14.3	10.3	8.9	4.8	4.1	5.6	3.4	3.8	3.7	2.9
2016-2020	17.6	31.1	22.3	15.6	13.6	10.9	9.6	8.0	7.3	8.4	6.0	6.0

2000–2005: Adapted from Hall et al, Pediatrics 2013,
2016–2020: CDC unpublished data

Percentage* of polymerase chain reaction test results positive for respiratory syncytial virus**, by MMWR week — National Respiratory and Enteric Virus Surveillance System, United States, July 2009–October 2023



Report was last updated on: 10/18//2023.
*All results presented are from nucleic acid amplification tests which represent >90% of the diagnostic tests reported to NREVSS. The last three weeks of data in 2023-24 may be less complete. NREVSS is an abbreviation for the National Respiratory and Enteric Virus Surveillance System. For more information on NREVSS, please visit National Respiratory and Enteric Virus Surveillance System | CDC.
**Respiratory syncytial virus types A and B are not shown separately in this report.
***The NREVSS surveillance season runs from the first week in July through June of the following year.

QUESTION

- Among infants hospitalized due to RSV, most are born premature or have chronic medical conditions

    a. True

    b. False

QUESTION

- Among infants hospitalized due to RSV, most are born premature or have chronic medical conditions

    a. True

    b. **False**

- A national study showed 79% of children hospitalized with RSV aged <2 years had no underlying medical conditions[1]

[1]Hall et al, Pediatrics, 2013;

Efficacy and Safety of Nirsevimab and Pfizer Maternal RSV Vaccine

Maternal RSV Vaccine and Infant Nirsevimab

- Two products are available to protect infants from severe RSV disease
- To protect infants in their first season:
  - Maternal vaccine (Abrysvo)*

    OR
  - Nirsevimab (Beyfortus)
- To protect eligible infants in their second season:
  - Nirsevimab (Beyfortus)

*An additional RSV vaccine (Arexvy, GSK) is not approved or recommended for use in pregnant people

https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761328s000lbl.pdf
https://www.fda.gov/media/168889/download

Nirsevimab Efficacy For Infants In First RSV Season

- Two randomized trials including pre-term and term infants
- Efficacy estimate evaluated through 150 days after injection in preventing:

Medically attended RSV lower respiratory tract infection (LRTI): **79.0%** (95% CI = 68.5%–86.1%)

RSV LRTI with hospitalization: **80.6%** (95% CI = 62.3%–90.1%)

Griffin MP, Yuan Y, Takas T, et al. https://doi.org/10.1056/NEJMoa1913556
Muller WJ, Madhi SA, Seoane Nuñez B, et al. https://doi.org/10.1056/NEJMc2214773
Jones JM, Fleming-Dutra KE, Prill MM, et al. https://www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm

Nirsevimab Safety

- Most reported adverse reactions were **injection site reactions** and **rash**

- Incidence of serious adverse events **not significantly different** between nirsevimab and placebo

Jones JM, Fleming-Dutra KE, Prill MM, et al. https://www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm
https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-08-3/02-RSV-jones-508.pdf

Maternal RSV Vaccine Efficacy (VE): Pfizer

- Multi-country randomized trial with vaccine administered during 24–36 weeks gestation
- Efficacy estimate evaluated through 180 days of birth in preventing:

VE against medically attended RSV-associated LRT:
51.3% (97.58% CI = 29.4%–66.8%)

VE against hospitalization for RSV-associated LRTI:
56.8% (99.17% CI = 10.1%–80.7%)

Fleming-Dutra KE, Jones JM, Roper LE, et al: https://www.cdc.gov/mmwr/volumes/72/wr/mm7241e1.htm

Maternal RSV Vaccine Safety

- Side effects tend to be mild or moderate, temporary, and like those experienced after other vaccinations.
- More preterm births and reports of hypertension during pregnancy, including pre-eclampsia were seen in the vaccine group than placebo group in clinical trials, but it is not known if this was related to the vaccine or simply due to chance.
  - Restricting vaccination to during 32 to 36 weeks gestation reduces the potential risk of preterm birth.
- ACIP determined benefits of maternal vaccination outweigh potential risks.

Fleming-Dutra KE, Jones JM, Roper LE, et al: https://www.cdc.gov/mmwr/volumes/72/wr/mm7241e1.htm

Maternal Vaccination Recommendations

Maternal Vaccine Recommendations

- Maternal vaccine is recommended for pregnant people during **32 through 36 weeks gestation**, with seasonal administration.
  - During **September through January** in most of the continental United States
  - In jurisdictions with seasonality that differs from most of the continental United States (e.g., Alaska, jurisdictions with tropical climates), providers should follow **state, local, or territorial guidance** on timing of administration

- Maternal Pfizer vaccine can be **simultaneously administered** with other indicated vaccinations.

Fleming-Dutra KE, Jones JM, Roper LE, et al: https://www.cdc.gov/mmwr/volumes/72/wr/mm7241e1.htm

Two Options To Prevent RSV Lower Respiratory Tract Infection In Infants

- Either maternal vaccination or use of nirsevimab in the infant is recommended to prevent RSV lower respiratory tract infection, but administration of both products is not needed for most infants.
- Healthcare providers of pregnant people should provide information on both products and consider patient preferences when determining whether to vaccinate the pregnant patient or to not vaccinate and rely on administration of nirsevimab to the infant after birth.

https://www.cdc.gov/mmwr/volumes/72/wr/mm7241e1.htm

QUESTION

- When in pregnancy is the Pfizer RSVpreF maternal vaccine recommended?
    a. Any time during pregnancy
    b. 24-36 weeks gestation
    c. 32-36 weeks gestation

QUESTION

- When in pregnancy is the RSV maternal vaccine recommended?
    a. Any time during pregnancy
    b. 24-36 weeks gestation
    c. 32-36 weeks gestation

- The Pfizer RSV vaccine is recommended to be given during 32 weeks and 0 days through 36 weeks and 6 days' gestation

Nirsevimab Recommendations

Assuming sufficient nirsevimab availability

Nirsevimab Timing: 2023-2024 Season

<u>2023-24 RSV season has started or expected to begin in next 1-2 months</u>: Nirsevimab administration to eligible children should begin as soon as it is available*

Continue to offer nirsevimab through <u>March</u> to eligible infants and children.*

*Areas with tropical climates or Alaska have seasonality that may differ from most of the continental United States, and should follow local guidance, including Florida, Hawaii, Guam, Puerto Rico, U.S. Virgin Islands, U.S.-affiliated Pacific Islands, and Alaska.

Jones JM, Fleming-Dutra KE, Prill MM, et al. https://www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm

Nirsevimab Recommendations: Infants <8 months

Infants born October 2023–March 2024

- Immunize **within 1 week** of birth
  - Administration can occur during the birth hospitalization or in the outpatient setting.
- Immunize infants with prolonged birth hospitalizations due to **prematurity** or other causes **shortly before or promptly after discharge**

Complete recommendations available at https://www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm and https://www.cdc.gov/mmwr/volumes/72/wr/mm7241e1.htm

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All other infants younger than age 8 months

- Administer as soon as nirsevimab is available if age of infant is **younger than 8 months** at the **time of immunization** assuming sufficient nirsevimab availability*

Complete recommendations available at https://www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm and https://www.cdc.gov/mmwr/volumes/72/wr/mm7241e1.htm

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All other infants younger than age 8 months

- Administer as soon as nirsevimab is available if age of infant is **younger than 8 months** at the **time of immunization** assuming sufficient nirsevimab availability*

If mother vaccinated 14 or more days prior to birth, nirsevimab not needed for most infants.

Complete recommendations available at https://www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm and https://www.cdc.gov/mmwr/volumes/72/wr/mm7241e1.htm

Circumstances for which nirsevimab can be considered when mother has received RSV vaccine ≥14 days prior to birth

- Nirsevimab can be considered in rare circumstances when, per the clinical judgment of the healthcare provider, the potential incremental benefit of administration is warranted. These include but are not limited to:
  - Infants born to pregnant people who may not mount an adequate immune response to vaccination (e.g., people with immunocompromising conditions) or who have conditions associated with reduced transplacental antibody transfer (e.g., people living with HIV infection)[1]
  - infants who might have experienced loss of maternal antibodies, such as those who have undergone cardiopulmonary bypass or extracorporeal membrane oxygenation[2]
  - Infants with substantial increased risk for severe RSV disease (e.g., hemodynamically significant congenital heart disease, intensive care admission and requiring oxygen at discharge)

1 Palmerira Clin Dev Immunol 2012. 2 Feltes J Pediatr 2003.

Nirsevimab Recommendations: Children 8–19 months

At-risk children **ages 8–19** months and entering **2nd RSV season**

- Administer as soon as nirsevimab is available if age is **8–19 months** at the time of immunization **and** is at **increased risk for severe disease** assuming sufficient nirsevimab availability*

Children with **chronic lung disease of prematurity** who required medical support any time during the 6-month period before the start of the second RSV season

Children with **cystic fibrosis** who either have manifestations of severe lung disease or weight-for-length <10th percentile

Children with severe **immunocompromise**

American Indian or **Alaska Native** children

Complete recommendations available at https://www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm and https://www.cdc.gov/mmwr/volumes/72/wr/mm7241e1.htm

*See https://emergency.cdc.gov/han/2023/han00499.asp for recommendations for healthcare setting with lack of sufficient nirsevimab

Limited Availability Of Nirsevimab

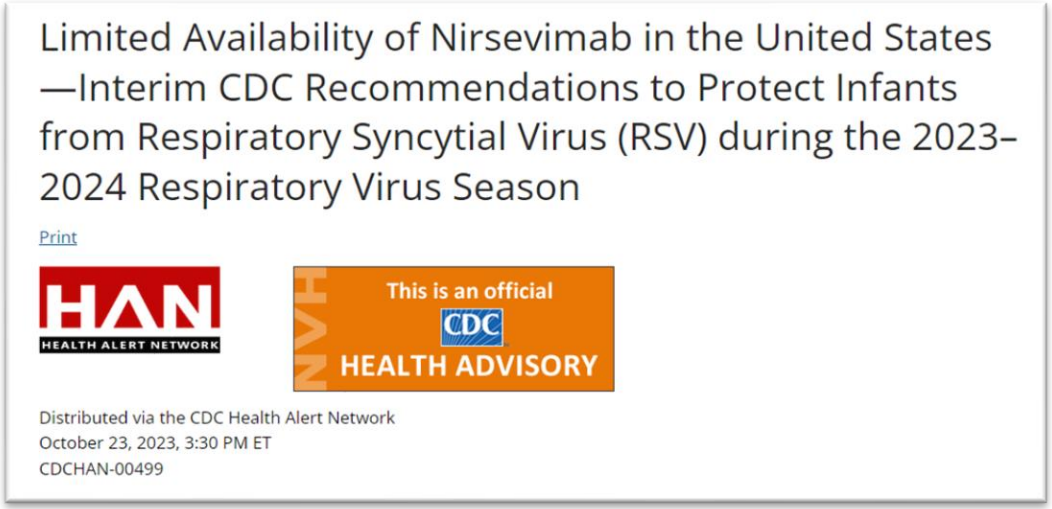
Nirsevimab availability is limited

- The manufacturer has reported a limited supply of nirsevimab, particularly 100mg dose prefilled syringes used for infants weighing ≥5 kg
- Based on manufacturing capacity and currently available stock, there are not sufficient 100mg dose prefilled syringes of nirsevimab to protect all eligible infants weighing ≥5 kg during the current RSV season.
- Supply of 50mg dose prefilled syringes may be limited during current season

https://www.news.sanofi.us/Sanofi-Beyfortus-Statement

CDC Health Advisory

- On October 23, 2023, CDC released a HAN Health Advisory describing interim recommendations to provide options for clinicians to protect infants from RSV in the context of a limited supply of nirsevimab


Limited Availability of Nirsevimab in the United States —Interim CDC Recommendations to Protect Infants from Respiratory Syncytial Virus (RSV) during the 2023–2024 Respiratory Virus Season

Print

HAN HEALTH ALERT NETWORK

This is an official CDC HEALTH ADVISORY

Distributed via the CDC Health Alert Network
October 23, 2023, 3:30 PM ET
CDCHAN-00499

https://emergency.cdc.gov/han/2023/han00499.asp

CDC Interim Recommendations For Healthcare Settings With Insufficient Nirsevimab Availability: 50 mg doses for infants weighing <5 kg

- Recommendations for the 50mg doses remain unchanged at this time
- Providers should encourage pregnant people to receive Pfizer's RSV maternal RSV vaccine (Abrysvo) during 32–36 weeks' gestation to prevent RSV-associated lower respiratory tract infection
- Potential for limited nirsevimab availability should be considered when deciding on maternal RSV vaccination or nirsevimab

https://emergency.cdc.gov/han/2023/han00499.asp

CDC Interim Recommendations For Healthcare Settings With Insufficient Nirsevimab Availability: 100 mg doses for infants weighing ≥5 kg

- In healthcare settings with limited availability of 100mg doses, prioritize infants at highest risk of severe RSV disease for receipt of 100mg nirsevimab doses
  - Young infants aged <6 months
  - American Indian or Alaska Native infants aged <8 months
  - Infants aged 6 to <8 months with conditions that place them at high risk of severe RSV disease:
    - Premature birth at <29 weeks' gestation
    - Chronic lung disease of prematurity
    - Hemodynamically significant congenital heart disease
    - Severe immunocompromise, severe cystic fibrosis (either manifestations of severe lung disease or weight-for-length less than 10th percentile)
    - Neuromuscular disease or congenital pulmonary abnormalities that impairs the ability to clear secretions

https://emergency.cdc.gov/han/2023/han00499.asp

CDC Interim Recommendations For Healthcare Settings With Insufficient Nirsevimab Availability: Prioritizing 50mg doses

- 50mg doses should be reserved only for infants weighing <5 kilograms
  - Avoid using two 50mg doses in place of a 100 mg dose for infants weighing ≥5 kg

- Follow AAP recommendations for palivizumab-eligible infants aged <8 months when the appropriate dose of nirsevimab is not available

https://emergency.cdc.gov/han/2023/han00499.asp
ACIP and AAP Recommendations for Nirsevimab | Red Book Online | American Academy of Pediatrics

CDC Interim Recommendations For Healthcare Settings With Insufficient Nirsevimab Availability: 200mg doses for children aged 8-19 months

- In healthcare facilities with limited availability of 100mg doses, for palivizumab-eligible children aged 8-19 months, providers should suspend the use of nirsevimab for the 2023–2024 season. These children should receive palivizumab per AAP recommendations.
- Continue offering nirsevimab to American Indian and Alaska Native children aged 8-19 months who
  - are not palivizumab-eligible

  and

  - who live in remote regions, where transportation of children with severe RSV for escalation of medical care is more challenging, or in communities with known high rates of RSV among older infants and toddlers

- https://emergency.cdc.gov/han/2023/han00499.asp
- ACIP and AAP Recommendations for Nirsevimab | Red Book Online | American Academy of Pediatrics
- Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection | Pediatrics | American Academy of Pediatrics (aap.org)

Implementing Respiratory Syncytial Virus (RSV) Immunizations in Your Practice

Sarah Meyer, MD MPH
Chief Medical Officer
Immunization Services Division

October 26, 2023

Two Options to Protect Infants and Young Children from RSV

Maternal immunization

Nirsevimab

Two Options to Protect Infants and Young Children from RSV

Maternal immunization

Nirsevimab

Pregnant patients and providers should take into account the limited availability of nirsevimab during the 2023-2024 season when making decisions about maternal RSV immunization

Immunizations to Prevent RSV Infection

Who, What, When, Where, and Why

	Who	What	When		Where	Why
Maternal RSV Immunization	 Pregnant people	 Pfizer RSV vaccine (Abrysvo)	 32 through end of 36th week	 September-January*	 Primarily outpatient clinics and pharmacies	 Protects infants from severe RSV from birth through first months of life

*Refer to local guidance, when applicable.

Immunizations to Prevent RSV Infection

Who, What, When, Where, and Why

	Who	What	When	Where	Why
Maternal RSV Immunization	 Pregnant people	 Pfizer RSV vaccine (Abrysvo)	 32 through end of 36th week	 September-January*	 Primarily outpatient clinics and pharmacies	 Protects infants from severe RSV from birth through first months of life
Nirsevimab	 Infants aged <8 months whose mothers did not receive RSV vaccine, children 8-19 months at increased risk	 Nirsevimab (Beyfortus) monoclonal antibody	 First week of life, or as entering RSV season	 October-March *	 Primarily birthing hospital and outpatient clinics	 Protects infants and young children from severe RSV in the months after immunization

*Refer to local guidance, when applicable.

Immunizations to Prevent RSV Infection

Who, What, When, Where, and Why

	Who	What	When	Where	Why
Maternal RSV Immunization	 Pregnant people	 Pfizer RSV vaccine (Abrysvo)	 32 through end of 36th week	 September-January*	 Primarily outpatient clinics and pharmacies	 Protects infants from severe RSV from birth through first months of life
Nirsevimab	 See Health Advisory for priority groups in the setting of limited nirsevimab during 2023-2024 season	 Nirsevimab (Beyfortus) monoclonal antibody	 First week of life, or as entering RSV season	 October-March*	 Primarily birthing hospital and outpatient clinics	 Protects infants and young children from severe RSV in the months after immunization

Health Alert Network (HAN) - 00499 | Limited Availability of Nirsevimab in the United States—Interim CDC Recommendations to Protect Infants from Respiratory Syncytial Virus (RSV) during the 2023–2024 Respiratory Virus Season

*Refer to local guidance, when applicable.

Implementing RSV Immunizations in Your Practice

- Ordering
- Costs and insurance coverage
- Storage, handling, and administration
- Patient education and counseling
- Documentation
- Special considerations for the Vaccines for Children program providers

Ordering RSV immunizations

- Order RSV immunizations through routine mechanisms (e.g., directly from the manufacturer, or wholesaler or distributer)
  - For Vaccines for Childrens (VFC) providers, order through state or local immunization program, as with other routine immunizations

- Ability to order nirsevimab doses may be limited at the time, particularly for the 100 mg dose

- Inquire with manufacturer for return or refund policies for expired or unused doses

Costs and Insurance Considerations

Maternal RSV Vaccine

- $295 per dose
- Insurance coverage:
  - Medicaid without cost-sharing for nearly all full-benefit adult beneficiaries with traditional Medicaid
  - VFC program for persons aged <19 years
  - Most private insurance plans required to cover, but have one year to do so

VFC | Current CDC Vaccine Price List | CDC

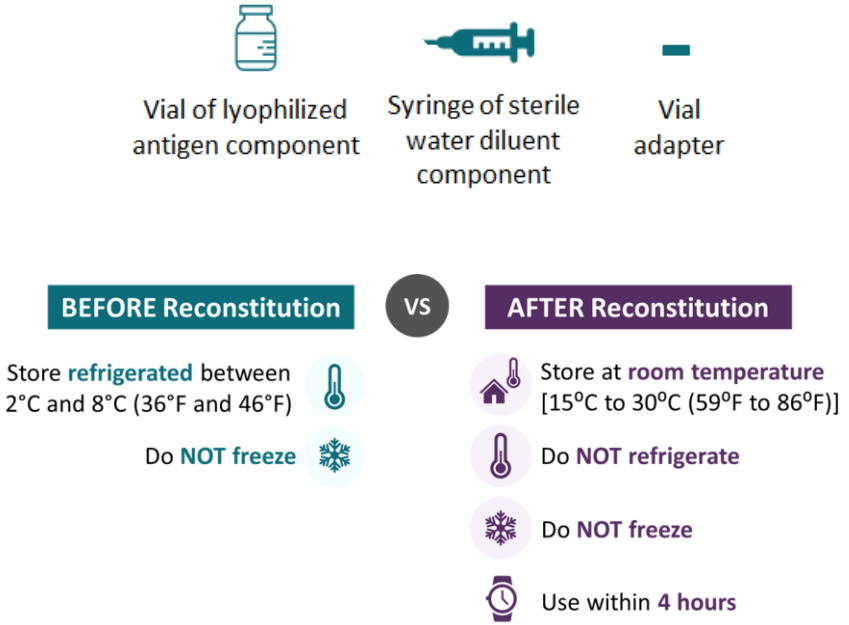
Nirsevimab

- $495 per dose (private sector cost)
- Payment flexibilities this season: 150 days for payment when ordering directly from the manufacturer
- Insurance coverage:
  - Covered under the Vaccines for Children (VFC) program
  - Most private insurance plans required to cover, but have one year to do so

Storage, Handling, and Administration of RSV Immunizations

Pfizer Maternal RSV Vaccine: Storage and Handling

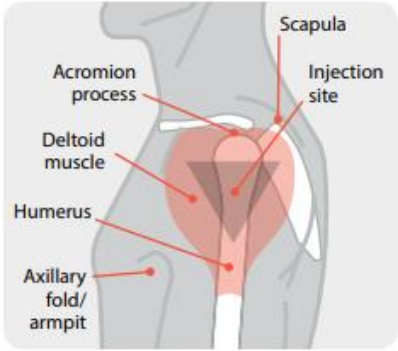
- Supplied as a 3-component kit
- Requires reconstitution
- Different storage and handling procedures before/after reconstitution



https://www.fda.gov/media/168889/download

Pfizer Maternal RSV Vaccine: Administration

- Route: Intramuscular injection
- Site: Deltoid muscle in the upper arm
  - Alternate: Vastus lateralis muscle of anterolateral thigh
- Dosage: 0.5 ml



Administer <u>ONLY</u> the Pfizer RSV vaccine (Abrysvo) to pregnant people. Do <u>NOT</u> administer the GSK vaccine (Arexvy)

https://www.fda.gov/media/168889/download

Nirsevimab: Storage and Handling

- Supplied as a:
  - **0.5 mL (50 mg)** prefilled syringe with **purple plunger rod**
  - **1 mL (100 mg)** prefilled syringe with **light blue plunger rod**

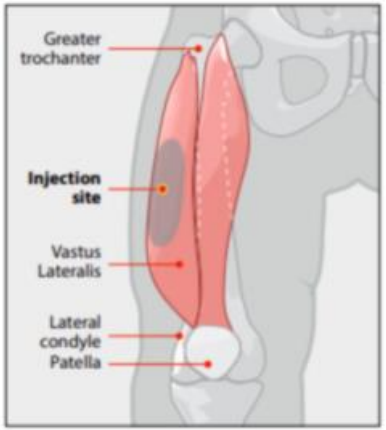
- Storage and handling
  - Store **refrigerated** between 2°C and 8°C (36°F and 46°F).
  - Use within **8 hours** of removing from refrigerator.
    - May store at room temperature [between 20°C and 25°C (68°F and 77°F)] for a maximum of 8 hours.
  - Do **NOT freeze**.
  - Do **NOT shake**.
  - Protect from **light**.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761328s000lbl.pdf

Nirsevimab: Administration

- Route: Intramuscular injection
- Site: Vastus lateralis muscle of anterolateral thigh
- Dosage: Dependent on weight

RSV Season	Body Weight the Day of Immunization	Number of Injections	Recommended Total Dosage
First	Less than 5 kg	One 50 mg prefilled syringe	0.5 mL (50 mg)
First	5 kg and greater	One 100 mg prefilled syringe	1 mL (100 mg)
Second	N/A	Two 100 mg prefilled syringes	2 mL (200 mg total)



https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761328s000lbl.pdf

Coadministration

Maternal RSV vaccine or nirsevimab can be administered with other recommended vaccines


YOU are patients' most trusted source of information on vaccines.

Patient Education and Counseling: Pfizer Maternal RSV Vaccine

- Either maternal RSV vaccine or infant nirsevimab is recommended for all infants, but administration of both products not needed for most infants
- Prenatal providers should discuss both products with pregnant people to aid in their decision-making, taking into account:
  - Relative advantages and disadvantages of each product
  - Patient preferences
  - Local availability of nirsevimab
- Prenatal providers who do not offer the maternal RSV vaccine in their practice should refer patients elsewhere for vaccination
  - Proactively provide a prescription if required by state law for vaccination in a pharmacy

Relative Advantages and Disadvantages of Each Product

	Advantages	Disadvantages
 Maternal RSV vaccine	• Immediate protection after birth • Might be more resistant to potential mutations in F protein	• Potentially reduced protection in some situations (e.g., pregnant person is immunocompromised or infant born soon after vaccination) • Potential risk for preterm birth and hypertensive disorders of pregnancy

Use of the Pfizer Respiratory Syncytial Virus Vaccine During Pregnancy for the Prevention of Respiratory Syncytial Virus–Associated Lower Respiratory Tract Disease in Infants: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023 | MMWR (cdc.gov)

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 Nirsevimab	• Protection from nirsevimab may wane more slowly than from maternal RSV vaccine • Direct receipt of antibodies rather than relying on transplacental transfer • No risk for adverse pregnancy outcomes	• Potentially limited availability during 2023–24 RSV season • Requires infant injection

Use of the Pfizer Respiratory Syncytial Virus Vaccine During Pregnancy for the Prevention of Respiratory Syncytial Virus–Associated Lower Respiratory Tract Disease in Infants: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023 | MMWR (cdc.gov)

Conversation Guide: RSV Immunization Decisions

"At this point in your pregnancy, you are eligible to get the RSV vaccine to protect your infant from severe respiratory illness.

RSV is a common seasonal viral infection that can cause pneumonia requiring hospitalization of babies. It can become very severe and make it hard for babies to get the oxygen they need. It is the most common cause of infant hospitalization in the U.S.

We actually have two options for preventing severe RSV illness in babies."

Conversation Guide: RSV Immunization Decisions

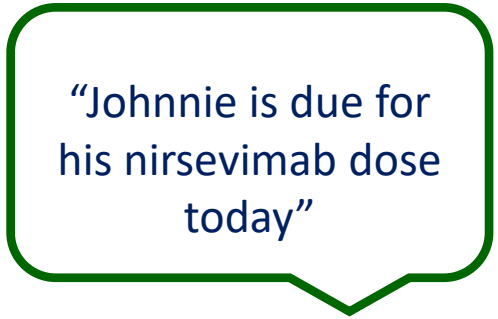
“One option is a new vaccine that we give you during pregnancy, which allows your immune system to protect the baby. The vaccine causes you to make antibodies that you pass to your baby through the placenta.

The other option called nirsevimab can be given to your baby after birth and works similarly to protect your baby from RSV illness after delivery.

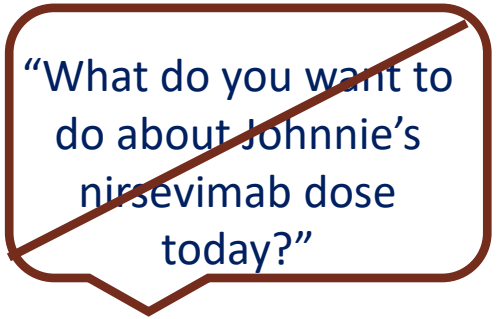
One or the other is recommended, but both are not needed for most babies. Keep in mind though that there may be limited availability of nirsevimab this season once your baby is born.”

Patient Education and Counseling: nirsevimab

- Counsel your patients about nirsevimab the same way you would for any other immunization
- If your practice does not carry or has insufficient supplies of nirsevimab, refer patients elsewhere in the community when feasible
- As of October 6, 2023, 2 new CPT codes available for the administration and counseling for nirsevimab



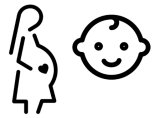
Presumptive approach

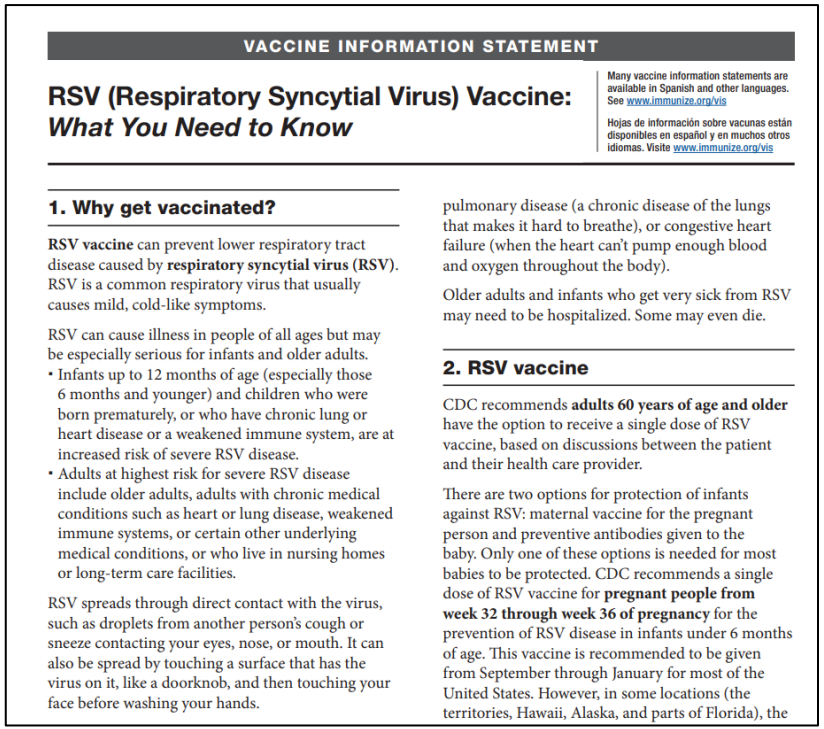


Participatory approach

Category I Immunization Long Code Descriptors | AMA (ama-assn.org)

Vaccine and Immunization Information Sheets





VACCINE INFORMATION STATEMENT

RSV (Respiratory Syncytial Virus) Vaccine:
What You Need to Know

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

RSV vaccine can prevent lower respiratory tract disease caused by **respiratory syncytial virus (RSV)**. RSV is a common respiratory virus that usually causes mild, cold-like symptoms.

RSV can cause illness in people of all ages but may be especially serious for infants and older adults.

- Infants up to 12 months of age (especially those 6 months and younger) and children who were born prematurely, or who have chronic lung or heart disease or a weakened immune system, are at increased risk of severe RSV disease.
- Adults at highest risk for severe RSV disease include older adults, adults with chronic medical conditions such as heart or lung disease, weakened immune systems, or certain other underlying medical conditions, or who live in nursing homes or long-term care facilities.

RSV spreads through direct contact with the virus, such as droplets from another person's cough or sneeze contacting your eyes, nose, or mouth. It can also be spread by touching a surface that has the virus on it, like a doorknob, and then touching your face before washing your hands.

pulmonary disease (a chronic disease of the lungs that makes it hard to breathe), or congestive heart failure (when the heart can't pump enough blood and oxygen throughout the body).

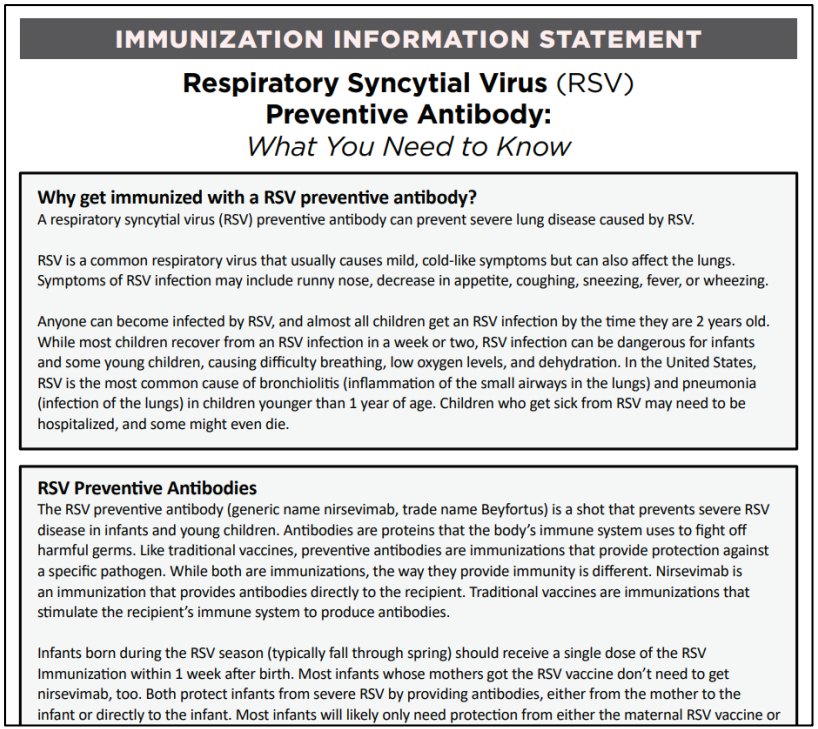
Older adults and infants who get very sick from RSV may need to be hospitalized. Some may even die.

2. RSV vaccine

CDC recommends **adults 60 years of age and older** have the option to receive a single dose of RSV vaccine, based on discussions between the patient and their health care provider.

There are two options for protection of infants against RSV: maternal vaccine for the pregnant person and preventive antibodies given to the baby. Only one of these options is needed for most babies to be protected. CDC recommends a single dose of RSV vaccine for **pregnant people from week 32 through week 36 of pregnancy** for the prevention of RSV disease in infants under 6 months of age. This vaccine is recommended to be given from September through January for most of the United States. However, in some locations (the territories, Hawaii, Alaska, and parts of Florida), the

[RSV Vaccine Information Statement | CDC]



IMMUNIZATION INFORMATION STATEMENT

Respiratory Syncytial Virus (RSV)
Preventive Antibody:
What You Need to Know

Why get immunized with a RSV preventive antibody?
A respiratory syncytial virus (RSV) preventive antibody can prevent severe lung disease caused by RSV.

RSV is a common respiratory virus that usually causes mild, cold-like symptoms but can also affect the lungs. Symptoms of RSV infection may include runny nose, decrease in appetite, coughing, sneezing, fever, or wheezing.

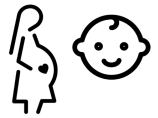
Anyone can become infected by RSV, and almost all children get an RSV infection by the time they are 2 years old. While most children recover from an RSV infection in a week or two, RSV infection can be dangerous for infants and some young children, causing difficulty breathing, low oxygen levels, and dehydration. In the United States, RSV is the most common cause of bronchiolitis (inflammation of the small airways in the lungs) and pneumonia (infection of the lungs) in children younger than 1 year of age. Children who get sick from RSV may need to be hospitalized, and some might even die.

RSV Preventive Antibodies
The RSV preventive antibody (generic name nirsevimab, trade name Beyfortus) is a shot that prevents severe RSV disease in infants and young children. Antibodies are proteins that the body's immune system uses to fight off harmful germs. Like traditional vaccines, preventive antibodies are immunizations that provide protection against a specific pathogen. While both are immunizations, the way they provide immunity is different. Nirsevimab is an immunization that provides antibodies directly to the recipient. Traditional vaccines are immunizations that stimulate the recipient's immune system to produce antibodies.

Infants born during the RSV season (typically fall through spring) should receive a single dose of the RSV Immunization within 1 week after birth. Most infants whose mothers got the RSV vaccine don't need to get nirsevimab, too. Both protect infants from severe RSV by providing antibodies, either from the mother to the infant or directly to the infant. Most infants will likely only need protection from either the maternal RSV vaccine or

[Immunization Information Sheet-RSV Preventive Antibody: What You Need to Know-September 25, 2023 (cdc.gov)]

Documentation of Immunizations Administered



Maternal RSV Vaccine

- Critically important to document receipt of maternal RSV vaccine as most infants of vaccinated mothers not recommended to receive nirsevimab
  - Immunization Information Systems (IIS)
  - Electronic Health Records (EHRs)
  - Written documentation for patient to bring to birthing hospital and pediatric provider visits

Nirsevimab

- Report to state IIS in accordance with state policies or laws for reporting of vaccine administration

Special nirsevimab considerations for VFC providers

National Center for Immunization and Respiratory Diseases

CDC's Vaccines for Children Program Addendum: Special Considerations for Nirsevimab

Updated 10/18/2023

Nirsevimab is an FDA-licensed monoclonal antibody that provides passive immunity against RSV-associated infection. On August 3, 2023, the Advisory Committee on Immunization Practices (ACIP) voted to recommend nirsevimab as an immunization for all infants aged <8 months, as well as some children up to age 20 months (see ACIP recommendations), and a VFC resolution was passed to include nirsevimab in the VFC program. This addendum provides supplemental information and guidance related to the addition of the nirsevimab immunization to the VFC formulary.

- Ramp-up period for private inventory requirements
- VFC-eligible patients remain the priority for VFC doses, but bi-directional borrowing between private and public stock allowed in certain situations (where allowed by jurisdictional policies)

CDC's Vaccines for Children Program Addendum: Special Considerations for Nirsevimab-October 18, 2023

Resources

- Healthcare Provider Toolkit: Preparing Your Patients for the Fall and Winter Virus Season
- Healthcare Providers: RSV Prevention Information for Infants and Young Children
- Healthcare Providers: RSV Vaccination for Pregnant People
- Options for Infant RSV Prevention At-a-Glance
- Frequently Asked Questions About RSV Immunization for Children 19 Months and Younger
- Respiratory Syncytial Virus (RSV) Preventive Antibody: Immunization Information Statement (IIS)
- Respiratory Syncytial Virus (RSV) Vaccine VIS

QUESTION

- Which of the following products are approved for use in pregnant people?

  A. GSK RSV vaccine (Arexvy)

  B. Pfizer RSV vaccine (Abrysvo)

  C. Nirsevimab, a preventive antibody (Beyfortus)

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- Which of the following products are approved for use in pregnant people?

  A. GSK RSV vaccine (Arexvy)

  B. Pfizer RSV vaccine (Abrysvo)

  C. Nirsevimab, a preventive antibody (Beyfortus)

  Only the Pfizer RSV vaccine is approved and recommended for use in pregnant people.

Updates to COVID-19 Vaccine Policy

Recommendations for children aged 6 months – 4 years without immunocompromise

Doses recommended:

- Initial series of 2 Moderna vaccine doses OR 3 Pfizer-BioNTech vaccine doses
- **Including at least 1 dose of 2023–2024 COVID-19 vaccine**

- All doses should be homologous (i.e., from the same manufacturer)
- All Moderna doses in ages 6 months – 11 years are now 25 µcg

Increased Flexibility for Interchangeability of COVID-19 Vaccines

Previous language:

- In the following exceptional situations, a different age-appropriate COVID-19 vaccine may be administered:
  - Same vaccine not available
  - Previous dose unknown
  - Person would otherwise not complete the vaccination series
  - Person starts but unable to complete a vaccination series with the same COVID-19 vaccine due to a contraindication

Updated language:

- In the following **circumstances**, an age-appropriate COVID-19 vaccine from a different manufacturer may be administered:
  - Same vaccine not available **at the vaccination site at the time of the clinic visit**
  - Previous dose unknown
  - Person would otherwise not **receive a recommended vaccine dose**
  - Person starts but unable to complete a vaccination series with the same COVID-19 vaccine due to a contraindication

Note: Submission of a Vaccine Adverse Event Reporting System (VAERS) report not needed in either scenario

Clinical Guidance for COVID-19 Vaccination | CDC

Additional Updates to Interim Clinical Considerations for COVID-19 Vaccines

- Updated guidance for children who transition during the initial COVID-19 vaccination series from age 4 years to age 5 years and children who are moderately or severely immunocompromised and transition from age 11 years to age 12 years to receive the age-appropriate dosage based on their age on the day of vaccination

Clinical Guidance for COVID-19 Vaccination | CDC

To Ask a Question

- Using the Zoom Webinar System
  - Click on the “Q&A” button
  - Type your question in the “Q&A” box
  - Submit your question

- If you are a patient, please refer your question to your healthcare provider.

- If you are a member of the media, please direct your questions to CDC Media Relations at 404-639-3286 or email media@cdc.gov.

Continuation Education

- All continuing education for COCA Calls is issued online through the CDC Training & Continuing Education Online system at https://tceols.cdc.gov/.
- Those who participate in today's COCA Call and wish to receive continuing education please complete the online evaluation by **Monday, November 27, 2023, with the course code WC4520-102623. The access code is COCA102623.**
- Those who will participate in the on-demand activity and wish to receive continuing education should complete the online evaluation between **October 26, 2023, and November 28, 2025, and use course code WD4520-102623. The access code is COCA102623.**
- Continuing education certificates can be printed immediately upon completion of your online evaluation. A cumulative transcript of all CDC/ATSDR CEs obtained through the CDC Training & Continuing Education Online System will be maintained for each user.

Today's COCA Call will be Available to View On-Demand

- **When:** A few hours after the live call ends*
- **What:** Video recording
- **Where:** On the COCA Call webpage https://emergency.cdc.gov/coca/calls/2023/callinfo_102623.asp

A transcript and closed-captioned video will be available shortly after the original video recording posts at the above link.

Upcoming COCA Calls & Additional Resources

- Continue to visit https://emergency.cdc.gov/coca/ to get more details about upcoming COCA Calls.

- Subscribe to receive notifications about upcoming COCA calls and other COCA products and services at emergency.cdc.gov/coca/subscribe.asp.

Thank you for joining us today!

http://emergency.cdc.gov/coca

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.